UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. GENENTECH, INC. Defendant.	Civil Action No. 11-CV-01156 (VB) ECF Case Jury Demand
GENENTECH, INC., Counter-Plaintiff, v. REGENERON PHARMACEUTICALS, INC. Counter-Defendant.	

GENENTECH, INC., Plaintiff, v. REGENERON PHARMACEUTICALS, INC., SANOFI-AVENTIS U.S. LLC, AND SANOFI-AVENTIS U.S. INC. Defendants.	Civil Action No. 11-CV-09463 (VB) ECF Case Jury Demand

JOINT RULE 26(f) REPORT AND DISCOVERY PLAN

Pursuant to Rules 16 and 26(f) of the Federal Rules of Civil Procedure, Genentech, Inc. ("Genentech"), Regeneron Pharmaceuticals, Inc. ("Regeneron"), and Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S. Inc. (collectively, "the Sanofi Defendants") submit the following Rule 26(f) Report and Discovery Plan (hereinafter "Discovery Plan"). This Discovery Plan addresses items 1-14 of the Court's standard Civil Case Discovery Plan and Scheduling Order ("Standard Scheduling Order"), which was attached to the Court's Notice of Initial Court Conference, filed October 21, 2011 in the 1156 action (Dkt. 30). The Discovery Plan also provides additional background information and addresses other pre-trial issues that the parties believe the Court may find helpful for the Initial Court Conference.

In this Discovery Plan, the parties have indicated where they have agreed on particular issues, and have, in Section B.5, set forth their respective positions where they have been unable to reach agreement after conferring. The parties will be prepared to address these positions and their relative merits at the Conference.

A. Factual Background of the Case

The 1156 Action

On November 19, 2010, Regeneron filed a complaint with this Court seeking a declaration that that no activities involving its VEGF Trap product infringe any valid claim of U.S. Patent Nos. 5,952,199; 6,100,071; 6,383,486; 6,897,294; and 7,771,721 (the "Davis-Smyth Patents"), all of which are owned by Genentech. *See Regeneron Pharmaceuticals, Inc. v. Genentech, Inc.*, no. 10-cv-08779-VB (S.D.N.Y.) ("Regeneron

I"). On January 11, 2011, Genentech moved to dismiss the Regeneron I complaint for lack of a justiciable controversy.

On February 18, 2011, Regeneron filed the complaint in the present matter ("Regeneron II"). The Regeneron II complaint is substantially similar to the complaint in Regeneron I, but includes additional factual allegations, including allegations about Regeneron's February 18, 2011 submission of its Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") to obtain approval to commercialize its VEGF Trap product. These allegations were intended to moot any issue as to whether a justiciable controversy exists between the parties.

On February 22, 2011, Regeneron filed a motion to supplement the complaint in Regeneron I seeking to add the same new factual allegations found in the Regeneron II complaint.

On April 11, 2011, the parties filed a Joint Stipulation and Proposed Order in which they agreed to dismiss without prejudice the complaint in Regeneron I and to proceed under the Regeneron II complaint filed in the present matter. The parties agreed that the stipulation mooted Genentech's motion to dismiss the Regeneron I complaint and Regeneron's motion for leave to supplement the Regeneron I complaint. Genentech also agreed to answer the Regeneron II complaint and not seek to transfer or to dismiss the Regeneron II complaint under Rule 12(b). The Court entered the joint stipulation on April 11, 2011.

Genentech filed an Answer and Counterclaim on April 25, 2011 and an Amended Answer and Counterclaim on May 11, 2011. Regeneron filed its Reply to the Amended Answer and Counterclaim on May 25, 2011.

On January 10, 2012, Genentech filed a motion for leave to file a Second Amended Answer and Counterclaim. The Court granted that motion, and Genentech filed its Second Amended Answer and Counterclaim on January 17, 2012. Regeneron filed its Reply to Genentech's Second Amended Answer and Counterclaim on February 14, 2012.

The 9463 Action

On December 23, 2011, Genentech filed a complaint with this Court seeking a judgment that Regeneron and the Sanofi Defendants infringe the U.S. Patent Nos. 6,100,071; 6,383,486; 6,897,294; and 7,771,721 (the "Davis-Smyth Patents"), all of which are owned by Genentech. *See Genentech, Inc. v. Regeneron Pharmaceuticals, Inc. et al.*, no. 11-cv-09463-VB (S.D.N.Y.). Regeneron and the Sanofi Defendants each filed Answers and Counterclaims on February 14, 2012. Genentech's filed its Replies to these Answers and Counterclaims on March 9, 2012.

The Parties' Positions

1. Genentech's Position

Genentech seeks a ruling that Regeneron and the Sanofi Defendants' manufacture, use, sale, offer for sale, promotion and marketing of a VEGF receptor decoy, including, but not limited to, the VEGF Trap product (collectively the "accused products"), will infringe the Davis-Smyth patents, except where Regeneron's exploitation, use, offer for sale and/or sale is solely for purposes of converting bulk and/or other unfinished VEGF Trap-Eye into a filled and/or finished form for re-importation into the United States for use, offer for sale, and/or sale in the United States for prevention or treatment of eye diseases and eye disorders in a human in the United States. Genentech has also counterclaimed against Regeneron that the Davis-Smyth

patents are valid and enforceable. In addition, Genentech seeks appropriate monetary relief to address such infringement by Regeneron and the Sanofi Defendants, and its defense of this action and reserves the right to seek other legal and equitable remedies that may be appropriate.

Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for more than 35 years, using human genetic information to discover, develop, manufacture and commercialize medicines to treat patients with serious or life-threatening medical conditions. Today, Genentech is among the world's leading biotechnology companies, with multiple products on the market and a promising development pipeline.

By the 1990s, Genentech was undertaking the critical ground-breaking research that underlies the Davis-Smyth patents. Ultimately, leveraging off of its historical expertise in developing antibody-based therapies, Genentech pursued an antibody approach to treating the very types of neoplastic and non-neoplastic conditions that VEGF Trap is intended to treat. Based on that strategy, Genentech has developed and marketed Lucentis and Avastin, respectively, for treating blindness and cancer.

Both Lucentis and Avastin are blockbuster biologics. Their commercial success is a reflection of the medical breakthroughs they represent. Indeed, Dr. Napoleone Ferrara, one of the inventors on the Davis-Smyth patents, is responsible for much of the underlying research led to the development of Avastin for treating certain cancers and Lucentis for treating age-related blindness.

Genentech's Davis-Smyth patents make a valuable and significant contribution to our understanding of how VEGF interacts, at the molecular level, with its native

receptors to mediate disease. They opened the door for creating VEGF receptor decoys like Regeneron's VEGF Trap for use in therapies.

Regeneron and the Sanofi Defendants were well aware of Genentech's emerging patent position when developing its VEGF Trap and used the teachings of these patents to develop their competing therapeutic. Regeneron and the Sanofi Defendants' ability to develop its VEGF Trap based on the teachings of the Davis-Smyth patents is a testament to how robust those patents' disclosures actually are.

2. Regeneron and the Sanofi Defendants' Position

Regeneron's VEGF Trap is a groundbreaking new medicine for treating various cancers and blinding eye diseases that was independently developed by Regeneron.

Unlike Genentech's Avastin and Lucentis products, which are antibody-based therapies, Regeneron's VEGF Trap is a non-antibody-based protein that mimics the naturally occurring VEGF receptor proteins found on the endothelial cell surface. Indeed, the Genentech Davis-Smyth patents do not even embrace antibody-based therapies.

Regeneron has already obtained FDA approval for, and launched, its Eylea® VEGF Trap product for treating the eye disease known as wet age-related macular degeneration, and Eylea® is experiencing a strong launch. Now, Regeneron is working with its collaboration partner, Sanofi, in the non-eye field on clinical trials for the use of their Zaltrap® VEGF Trap product for the treatment of various cancers. A BLA was submitted by Sanofi in February of this year for the use of Zaltrap® to treat previously-treated metastatic colorectal cancer, and a decision by the FDA is expected sometime in 2012. The Genentech Davis-Smyth Patents do not describe VEGF Trap or the VEGF Trap technology, and those patents never led to any viable clinical drug candidates.

Indeed, Genentech abandoned the Davis-Smyth line of research in favor of an antibody-based approach. But after Regeneron first disclosed VEGF Trap to the public, Genentech changed the scope of its Davis-Smyth Patent claims in an effort to capture rights to Regeneron's new technology. Regeneron and the Sanofi Defendants do not agree that VEGF Trap infringes any valid claim of the Davis-Smyth Patents, because (among other reasons) if the claims are read to cover VEGF Trap, then they encompass subject matter that is not supported by the Davis-Smyth Patents and therefore fail to satisfy conditions of patentability under the Patent Act.

In addition to seeking a declaration that no activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth Patents, Regeneron and the Sanofi Defendants also seek attorneys' fees and costs, and any further relief the Court may deem just and proper.

B. Rule 26(f) Issues

1. What changes should be made in the timing, form, or requirements for disclosures under Rule 26, including a statement of when initial disclosures were made or will be made.

Genentech and Regeneron have already exchanged initial disclosures in the 1156 action. The parties in the 9463 action (Genentech, Regeneron, and the Sanofi Defendants) will exchange initial disclosures on or before March 15, 2012.

2. The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused upon particular issues.

a. Discovery Needed

Genentech intends to seek discovery directed to, among other things:

- The accused products, including, but not limited to: (a) their research, development, manufacture, sale, offer for sale, marketing and promotion by or on behalf of Regeneron or a third-party; (b) the properties the accused products possess and the

results they can achieve; and (c) the uses and applications to which the accused products can be/are put;

- Regeneron and the Sanofi Defendants' activities relating to the accused products for the purpose of proving that Regeneron or a third-party has infringed, or will infringe, directly and indirectly, the Davis-Smyth patents;
- Discovery relating to Regeneron, the Sanofi Defendants, Genentech, or third-parties; and the Davis-Smyth patents;
- Regeneron and the Sanofi Defendants' contentions regarding non-infringement of the Davis-Smyth patents;
- Regeneron and the Sanofi Defendants' contentions regarding invalidity of the Davis-Smyth patents;
- Regeneron and the Sanofi Defendants' knowledge and consideration of the Davis-Smyth patents;
- Regeneron and the Sanofi Defendants' prayer for an award of costs, and fees or any other monetary or equitable remedy;
- Discovery relating to damages and other remedies, either legal or equitable, to which Genentech may be entitled;
- Any other subject reasonably related to the allegations presented in the lawsuit.

Regeneron and the Sanofi Defendants intend to seek discovery directed to, among other things:

- The Davis-Smyth Patents, including, but not limited to, alleged conception, reduction to practice, purported diligence, research, development, prosecution, and enforcement;
- Certain products and drug candidates from Genentech, including, but not limited to, Lucentis and Avastin;
- Relevant research and development at Genentech and by third parties;
- Discovery relating to Regeneron, Sanofi Defendants, VEGF Trap, and third parties;
- Genentech's contentions regarding alleged infringement and validity of the Davis-Smyth Patents;
- Damages and other monetary or equitable remedies which Genentech seeks in this action;

- Any other subject reasonably related to any allegation, prayer for relief, claim or defense in this action.

b. Scheduling

Event	Date
Genentech's Disclosure of Asserted Claims and Infringement Contentions (see Exhibit A)	May 3, 2012
Regeneron and the Sanofi Defendants' Invalidity Contentions (See Exhibit B)	June 28, 2012
Exchange of identification of claim terms to be construed	July 26, 2012
Amendment of Pleadings and Joinder of New Parties	August 9, 2012
Exchange of proposed constructions of claim terms to be construed and identification of intrinsic and extrinsic evidence to be relied upon	September 7, 2012
Deadline by which the parties are to meet and confer to determine where there is agreement and disagreement on how terms should be construed	September 27, 2012
Opening Consolidated *Markman* Briefs	November 20, 2012
Close of Claim Construction Discovery	January 18, 2013
Answering Consolidated *Markman* Briefs	February 1, 2013
Consolidated *Markman* Hearing	February 22, 2013, or to be set by the Court
Completion of Fact Discovery (all interrogatories, requests for admissions, and requests for production shall be served at least 30 days before the close of fact discovery; fact depositions must be completed by the close of fact discovery; assumes the Court's Claim Construction Order issues 60 days before this period closes; if not, then a supplemental fact discovery should be provided to enable the parties to take into account the Court's Order, which period should last for 60 days following the entry of the Order, and dates for expert reports, expert discovery, and summary judgment should be adjusted accordingly)	April 1, 2013
Opening Expert Reports (on issues on which party bears the burden of proof)	May 1, 2013

Event	Date
Responsive Expert Reports	June 1, 2013
Rebuttal Expert Reports	July 2, 2013
Completion of Expert Discovery	August 10, 2013
Last Day to File Summary Judgment Motions	September 13, 2013
Pretrial Conference	To be set by the Court
Trial	To be set by the Court

The parties do not presently contemplate filing any motions in the near term.

c. The Standard Scheduling Order

Many of the deadlines contemplated in the Court's Standard Scheduling Order are addressed in the foregoing table, including items 3-5 (deadlines for joinder, amending the pleadings, and serving interrogatories), 7 (completing fact depositions), and 9-15 (serving requests to admit, exchanging expert reports, completing expert depositions, completing all discovery, and moving for summary judgment).

Insofar as the Standard Order raises other items, they are discussed immediately below:

- Item 1 (proceeding before a Magistrate Judge): The parties do not consent to conducting all further proceedings before a Magistrate Judge.
- Item 2 (jury trial): The parties intend this case to be tried to a jury.
- Item 5 (interrogatories): The parties agree that L.R. 33.3 shall not apply to these proceedings.
- Item 6 (serving document requests): The point is moot with respect to the 1156 action as the parties already have served document requests on each other. With respect to the 9463 action, the parties shall serve their first requests for production no later than March 20, 2012.
- Items 7a-c (depositions):

(a) The parties acknowledge that, the default agreement is that depositions shall not be held until all parties have responded to any first requests for production of documents unless the parties agree otherwise or the Court so orders. The parties will negotiate in good faith as to whether the default agreement should be modified.

(b) Depositions shall proceed concurrently.

(c) The parties agree that non-party depositions need not be deferred until party depositions have been taken.

- Item 8 (expert interrogatories): The provision is not relevant to these proceedings.

The parties do not presently contemplate filing any motions in the near term.

d. Format of the Consolidated *Markman* Hearing

The parties propose to confer regarding the format of the consolidated *Markman* hearing and to submit a proposal to the Court no later than December 13, 2012. The proposal shall include (1) the estimated length of the hearing; (2) whether live testimony will be offered; and (3) how the parties intend to educate the Court on the technology at issue.

To the extent that a party intends to rely upon extrinsic evidence, including expert testimony, then at the same time the parties exchange their proposed construction of claim terms on September 7, 2012, that party shall also identify all references from the specification or prosecution history that support its proposed construction and designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art, and testimony of expert witnesses. Extrinsic evidence shall be identified by production number or by producing a copy if not previously produced.

With respect to any expert testimony, the identifying party shall identify any such expert witness it may rely upon in support of one or more of its proposed constructions

and identify which of its proposed constructions any such witness may be offered on. The party relying on an expert witness during claim construction shall make the expert available for deposition at a mutually agreeable place and time that is sufficiently before the close of Claim Construction Discovery on January 11, 2013. Any such expert deposition taken shall not exceed 7 hours and shall not count against the party's allotment of deposition hours discussed below. The party shall also provide a declaration on behalf of the supporting expert witness(es) with its opening brief on claim construction, setting forth the proposed testimony and any opinions to be offered by such a witness in connection with claim construction.

3. *Any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced.*

The parties to the 1156 action have already come to some initial agreements regarding the production of electronically stored information, discussed below. The parties to that action and the 9463 action will meet and confer as to whether and to what extent those agreements should be modified so that omnibus agreements can be reached that apply to both actions, and submit such initial agreements by March 23, 2012.

The parties to the 1156 action propose to produce electronically stored information in TIFF format, accompanied by a load file with searchable text, with suitable TIFF image format specifications to be exchanged between the parties by December 8, 2011 and with subsequent modifications to such specifications reasonably allowed. The parties will negotiate in good faith regarding the nature and extent to which any metadata is to be included in the load files. Notwithstanding the foregoing, the parties agree to preserve metadata and for good cause, a party shall be entitled to the requested metadata associated with that TIFF file.

The parties to the 1156 action also recognize that certain documents may be more easily reviewed in native format, *e.g.*, spreadsheets, or input to or output from a computer program. The parties agree that if a party can demonstrate good cause for receiving a particular document in native format, such document will be produced in that form.

Finally, the parties to the 1156 action recognize that it may be unreasonably burdensome and otherwise inappropriate to preserve, search, collect, or produce certain forms of electronically stored information. Such information may include: voicemail messages; random access memory; instant messages and chats; information from Blackberry or other handheld devices that is not duplicative of data stored on e-mail servers; dynamic fields of databases or log files that are not stored or retained in the usual course of business; optical, tape, or other sequential backup systems; and any information created or copied during the routine, good-faith performance of processes for the deployment, maintenance, retirement, or disposition of computer equipment.

The parties to the 1156 action agree to negotiate in good faith regarding whether and to what extent they will need to preserve, search, collect, or produce particular forms of electronically stored information, and regarding any relevant criteria, such as search terms, date ranges, and custodians, to facilitate collecting discoverable electronic data.

4. *Any issues about claims of privilege or of protection as trial-preparation materials, including—if the parties agree on a procedure to assert these claims after production—whether to ask the court to include their agreement in an order.*

The parties agree that draft expert reports and communications between counsel and their experts shall not be discoverable. Notwithstanding, the following facts are discoverable: (i) an expert's compensation for his/her study or testimony; (ii) facts or data that the party's attorney provided and that the expert considered in forming the

opinions to be expressed; or (iii) assumptions that the party's attorney provided and that the expert relied on in forming the opinions to be expressed.

On March 1, 2012, the parties submitted a Stipulated Protective Order to the Court in the 1156 and 9463 actions that supersede the Protective Order previously entered by the Court in the 1156 action. The Court entered those Stipulated Protective Orders on March 5, 2012. Those Protective Orders address, inter alia, issues associated with inadvertent production.

The parties agree to meet and confer regarding the scope, content, and exchange of privilege logs, including regarding categories of documents and information immune from discovery that the parties need not log, and will submit a proposal (or any disputes regarding the matter that have arisen to date) to the Court by April 30, 2012.

5. *What changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed.*

The parties have agreed on many aspects of how discovery should be conducted in the case but disagree on the amount of discovery each side should be entitled to. The areas of agreement and disagreement are set forth below:

A. Requests for Admission

The parties agree that there should be no limitation on the number of requests to admit that can be served to establish the authentication or admissibility of documents. The parties disagree, however, on the number of requests to admit each side (i.e., Genentech vs. Regeneron and the Sanofi Defendants) should otherwise be limited to serve:

- **Genentech's Proposal.** Genentech shall be limited to serving a total of 225 requests to admit on Regeneron and the Sanofi defendants collectively. Regeneron and the

Sanofi Defendants shall be collectively limited to serving between them a total of 150 requests to admit on Genentech. Each party shall endeavor not to propound duplicative requests to admit on any party.

- **Regeneron and the Sanofi Defendants' Proposal.** Each side shall be limited to 200 requests to admit, i.e., Genentech may collectively serve 200 requests to admit on Regeneron and the Sanofi Defendants; and Regeneron and the Sanofi Defendants collectively may serve between them 200 requests to admit on Genentech. Each party shall endeavor not to propound duplicative requests to admit on any party.

B. Interrogatories

The parties agree that the provisions of Local Civil Rule 33.3 shall not apply to this case and, further that Regeneron and the Sanofi Defendants' Disclosures of Asserted Claims and Infringement Contentions and Plaintiff's Invalidity Contentions, as set forth in the schedule above and in Exhibits A and B, shall not be considered interrogatory responses and therefore do not count toward each party's interrogatory limit. The parties disagree, however, on the number of interrogatories each side (i.e., Genentech vs. Regeneron and the Sanofi Defendants) should be limited to:

- **Genentech's Proposal.** Genentech shall be limited to collectively serving a total of 48 interrogatories on Regeneron and the Sanofi Defendants. Regeneron and the Sanofi Defendants shall be collectively limited to serving a total of 32 interrogatories between them on Genentech.
- **Regeneron & the Sanofi Defendants' Proposal.** Each side shall be limited to a total of 48 interrogatories. Genentech shall be entitled to serve 48 interrogatories collectively on Regeneron and the Sanofi Defendants and Regeneron and the Sanofi

Defendants shall be collectively entitled to serve between them 48 interrogatories on Genentech. Each party shall endeavor not to propound duplicative interrogatories on any other party.

C. Depositions

Insofar as fact depositions are concerned, the parties have reached several agreements, including that : a) they are not limited to 10 depositions per side; b) depositions of fact witnesses shall not exceed 7 hours of time on the record, except that any named inventor of the Davis-Smyth Patents may be deposed for up to 14 hours on the record by Regeneron and the Sanofi Defendants collectively.

The parties also acknowledge that, the default agreement is that depositions shall not be held until all parties have responded to any first requests for production of documents unless the parties agree otherwise or the Court so orders. The parties will negotiate in good faith as to whether the default agreement should be modified. Depositions shall proceed concurrently. Finally, the parties agree that non-party depositions need not be deferred until party depositions have been taken.

The parties further agree that the hours limit for fact discovery is exclusive of expert depositions, and that the expert deposition limits discussed below are exclusive of deposition time for expert depositions occurring before the close of Claim Construction Discovery. Unless otherwise ordered by the Court or agreed to by the parties, each expert offered by one or more of the parties shall be deposed for no more than 7 hours on the record by either: (a) Genentech; or (b) Regeneron and the Sanofi Defendants collectively. To the extent one or more of the parties believes that additional deposition time with an expert is warranted, the parties shall meet and confer in a timely fashion, in

an attempt to resolve the issue. If the parties are unable to reach agreement after conferring, they shall seek the Court's assistance promptly regarding any additional expert deposition time that a party believes is needed.

The parties disagree, however, on the total number of deposition hours each should be entitled to:

- **Genentech's Proposal.** For depositions of both party and non-party fact witnesses, the following limits of time on the record shall apply: Genentech shall be permitted 225 hours on the record, including 30(b)(6) witnesses and non-party witnesses. Regeneron and the Sanofi Defendants shall be collectively permitted 175 hours on the record between them, including 30(b)(6) witnesses and non-party witnesses.
- **Regeneron & the Sanofi Defendants' Proposal.** For depositions of both party and non-party fact witnesses, the following limits of time on the record shall apply: Each side (i.e., Genentech vs. Regeneron and the Sanofi Defendants) shall be permitted 175 total hours on the record, including 30(b)(6) witnesses and non-party witnesses.

6. *Any other orders that the court should issue under Rule 26(c) or under Rule 16(b) and (c).*

The parties reserve the right to bring any other matters to the Court's attention should any issues arise as the facts and arguments are developed.

Dated: March 15, 2012

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